K041360

MAY - 5 2005

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Section C.
510(k) Summary

Date of Application: May 10, 2004

1. 510(k) Summary of the Safety and Effectiveness of Aldahol III High-Level Disinfectant, a liquid chemical sterilant and high-level disinfectant.

a. Applicant/Sponsor

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b. Application Correspondent

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c. Name of the Device:

Trade Name: Aldahol III High-Level Disinfectant
Common Name: Liquid Chemical Sterilant and High-Level Disinfectant
Classification Name: Not Classified

d. Predicate Name:

Cidex Activated Dialdehyde Solution

e. Summary of the substantial equivalence (SE) of Aldahol III High-Level Disinfectant to Cidex Activated Dialdehyde Solutuion.

Aldahol III High-Level Disinfectant and the predicate, Cidex Activated Dialdehyde Solution, are both glutaraldehyde-based disinfectants intended for the sterilization or high-level disinfection of reusable, clean, heat-sensitive devices. The glutaraldehyde concentration of both of these products is in the range of 2.4

to 3.4%. When activated, both products have alkaline pH values. Cidex activated Dialdehyde Solution is a legally marketed product. For these reasons Aldahol III High-Level Disinfectant is substantially equivalent to Cidex Activated Dialdehyde Solution.

f. Summary description of Aldahol III High-Level Disinfectant.

It was discovered that relatively low concentrations of alcohol enhance the mycobactericidal (TB) activity of glutaraldehyde. When activated with buffer salts to an alkaline pH value of about 7.6, the glutaraldehyde concentration of Aldahol III High-Level Disinfectant can remain constant over a 14-day use and reuse life. The combination of stable alkaline glutaraldehyde at about 3.4%, plus about 25% isopropanol provides a solution able to provide high-level disinfection with an exposure of 10.0 min at 20 C.

g. Summary of the intended use of Aldahol III High-Level Disinfectant.

Activated Aldahol III High-Level Disinfectant is intended for use and reuse for 14 days, or until a glutaraldehyde monitor indicates that the glutaraldehyde has declined to 2.1%, whichever comes first, for the high-level disinfection or sterilization of reusable, clean, heat-sensitive devices. The exposure for high-level disinfection is 10.0 min at 20 C, and the exposure for sterilization is 10.0 hrs at 20 C. Aldahol III High-Level Disinfectant can be used in an Automatic Endoscope Reprocessing (AER) machine where approved by the manufacturer of the AER.

h. Summary of the technological characteristics of Aldahol III High-Level Disinfectant in Comparison to Cidex Activated Dialdehyde Solution.

Aldahol III High-Level Disinfectant initially contains about 3.4% glutaraldehyde, and the glutaraldehyde concentration remains constant, independent of inadvertent dilution during use and reuse, during 14 days post-activation. By comparison, about 40% of the initial glutaraldehyde concentration of Cidex Solution is lost during 14 days post-activation, independent of use and reuse. For the purpose of enhanced mycobactericidal (TB) activity, Aldahol III High-Level Disinfectant contains about 25% isopropanol. Cidex Solution does not contain alcohol.

i-1. Summary of the Association of Official Analytical Chemists (AOAC) Use Dilution Tests.

Stainless steel penicylinders were labeled with cultures of Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa containing 5% animal serum, and tested according to the methods of the AOAC Use Dilution Tests 955.14, 955.15, and 964.02. When exposed to Aldahol III High-Level Disinfectant (HLD) at a worst case glutaraldehyde concentration of 2.0%, from a

14-day EPA Re-Use Test, all (100%) of the bacteria-labeled cylinders were disinfected following exposures of 3.0, 5.0, and 10.0 min at 20 C.

i-2. Summary of the results of fungicidal tests using worst case Aldahol III HLD.

Cultures of Trichophyton mentagrophytes, Aspergillus niger, or Candida albicans with 5% animal serum were tested against worst case Aldahol III High-Level Disinfectant at 2.0% glutaraldehyde from a 14-day EPA Re-Use Test according to the methods of the AOAC Fungicidal Test 955.17. All of these surrogate fungi were killed with exposures of 3.0, 5.0, and 10.0 min at 20 C.

i-3. Summary of the results of virucidal tests using worst case Aldahol III HLD.

Poliovirus type 1, Influenza A Virus, Herpes Simplex Virus type 1, and Adenovirus type 2, all containing 5% animal serum, were killed within the limits of detection with an exposure for 5.0 min at 20 C to Aldahol III HLD from a 14-day EPA Re-Use Test further diluted to 2.0% glutaraldehyde.

i-4. Summary of the results of mycobactericidal tests using worst case Aldahol III HLD.

Worst case Aldahol III HLD from a 14-day EPA Re-Use Test, further diluted to 2.0% glutaraldehyde, killed 6 log 10 of M. terrae with 5% animal serum, within 10.0 min at 20 C.

i-5. Summary of studies to determine the sterilization exposure for Aldahol III HLD.

Aldahol III HLD from an EPA 14-day Re-Use Test, further diluted to 2.0% glutaraldehyde, was tested against 40 spore-labeled carriers with exposures of 4.0, 6.0, 8.0, and 10.0 hrs at 20 C, according to the methods of the AOAC Sporicidal Test 966.04. Four (4) cylinders labeled with C. sporogenes were positive out of 40 tested with an exposure of 4.0 hrs at 20 C. All other spore-labeled carriers at all other exposure times were disinfected.

i-6. Summary of the results from a full three Lot test of Aldahol III HLD by the AOAC Sporicidal Test 966.04.

Three Lots of Aldahol III HLD from a 14-day EPA Re-Use, further diluted to 2.0% glutaraldehyde, passed the AOAC Sporicidal Test 966.04 with an exposure of 10.0 hrs at 20 C.

i-7. Summary of the results from a Confirmatory Sporicidal Test with Aldahol III HLD.

Aldahol III HLD from an EPA 14-day Re-Use Test, further diluted to 2.0% glutaraldehyde, passed a Confirmatory AOAC Sporicidal Test 966.04 with an exposure of 10.0 hrs at 20 C.

i-8. Summary of the results of simulated use tests with flexible endoscopes labeled with M. terrae and exposed to Aldahol III HLD.

The biopsy channels of flexible endoscopes were labeled with a culture of M. terrae with 5% animal serum and dried for 60.0 min. The M. terrae-labeled endoscopes were then exposed to worst case Aldahol III HLD from a 14-day EPA Re-Use Test, further diluted to 2.0% glutaraldehyde, for 5.0 min at 20 C. At least 6 log 10 of the M. terrae was killed by the Aldahol III HLD.

j. Summary of the results of clinical in-use tests with Aldahol III HLD.

Various colonoscopes and gastroscopes as received directly from patients at an endoscopy clinic, and cleaned, but not disinfected, according to the standard cleaning procedures of the clinic, were exposed for 5.0 min at 20 C to worst case Aldahol III HLD from a 14-day EPA Re-Use Test, further diluted to 2.0% glutaraldehyde. No (zero) bacteria were recovered from these endoscopes after the exposure to Aldahol III HLD.

k. Summary of the conclusions drawn from the in-vitro, simulated use tests, and clinical in-use tests of Aldahol III HLD that demonstrate that it is as safe, and as effective, or more effective, than Cidex Activated Dialdehyde Solution.

We conclude that Aldahol III HLD is as safe as Cidex Activated Dialdehyde Solution because Aldahol III HLD contains about the same concentration of glutaraldehyde as Cidex solution. We conclude that Aldahol III HLD is as antimicrobial, or more antimicrobial, than Cidex Solution because the glutaraldehyde in activated Aldahol III HLD is stable as compared to Cidex Solution, and because Aldahol III HLD contains isopropanol that enhances the kill of mycobacteria by glutaraldehyde.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Healthpoint, Limited
C/O Dr. Norman Miner
MicroChem Laboratory, Incorporated
1107-C South Airport Circle
Euless (Dallas), Texas 76040

Re: K041360
Trade/Device Name: Aldahol III High-Level Disinfectant
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: April 11, 2005
Received: April 12, 2005

Dear Dr. Miner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 041360

Device Name: Aldahol III High-Level Disinfectant

Indications For Use:

Sterilization: Aldahol III High-Level Disinfectant is a sterilant intended for the sterilization of reusable, clean, heat-sensitive medical devices when used as directed at or above its minimum recommended concentrations (MRC) of 2.1% alkaline glutaraldehyde and 15.0% isopropanol with an exposure of 10.0 hrs at 20 C.

High-Level Disinfection: Aldahol III High-Level Disinfectant is a high-level disinfectant intended for the disinfection of reusable, clean, heat-sensitive medical devices when used as directed at or above its MRC of 2.1% alkaline glutaraldehyde and 15.0% isopropanol with an exposure of 10.0 min at 20 C.

Sheila A Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 041360

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)